

**REMARKS****Claim amendments**

Claims 39-43, 54-58 and 68-86 have been canceled. Claims 36, 37 and 53 have been amended to delete the phrase “a homolog thereof”. Claim 52 has been amended to provide proper antecedent basis. No new matter has been added.

Applicants reserve the right to file a continuing application or take other appropriate action as deemed necessary to protect the inventions of the canceled claims.

**Objection under 35 U.S.C. §132**

The Amendment filed June 3, 2003 is objected to under 35 U.S.C. §132 because it is the Examiner’s opinion that the language “a homolog thereof” and “homolog” is not supported by the original disclosure (Office Action, page 2).

The language “a homolog thereof” and “homolog” of SEQ ID NO: 8 has been deleted from the claims, thereby obviating the objection.

**Rejection of Claims 36, 53, 39, 40, 43, 54, 55, 58, 68, 73, 74 and 77 under 35 U.S.C. §112, first paragraph**

Claims 36, 53, 39, 40, 43, 54, 55, 58, 68, 73, 74 and 77 are rejected under 35 U.S.C. §112, first paragraph “as failing to comply with the written description requirement” (Office Action, page 3). The Examiner states that the language “a homolog thereof” and “homolog” is not supported by the original disclosure (Office Action, page 3).

Claims 39-43, 54-58 and 68-86 have been canceled, and the language “a homolog thereof” has been deleted from Claims 36 and 53, thereby obviating the rejection.

**Rejection of Claims 36-86 under 35 U.S.C. §112, second paragraph**

Claims 36-86 are rejected under 35 U.S.C. §112, second paragraph “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention” (Office Action, page 3). The Examiner states that Claims 36, 39, 40, 43, 53, 54, 55, 58, 68, 73, 74 and 77 “are vague and indefinite in that the metes and bounds of ‘homolog’ are not defined” (Office Action, page 3).

Claims 39-43, 54-58 and 68-86 have been canceled, and the language “a homolog thereof” has been deleted from Claims 36, 37 and 53, thereby obviating the rejection.

Rejection of Claims 68-86 under 35 U.S.C. §112, first paragraph

Claims 68-86 are rejected under 35 U.S.C. §112, first paragraph “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention” (Office Action, page 4).

Claims 68-86 have been canceled, thereby obviating the rejection.

Rejection of Claims 36-40, 44-46, 50, 51, 59-61 and 65-67 under the judicially created doctrine of obviousness-type double patenting

Claims 36-40, 44-46, 50, 51, 59-61 and 65-67 are rejected under the judicially created doctrine of obviousness-type double patenting “as being unpatentable over claims 43-52 of U.S. Patent No. 6,338,952 in view of Siegel et al. (US Patent No. 6,495,347)” (Office Action, page 5). It is the Examiner’s opinion that based on the cited references, it would have been obvious “to make [an] immunogenic composition comprising a portion of HSP70, SEQ ID NO: 8 homolog and conjugate it with any viral antigen to induce an enhanced CD8+ T cell mediated CTL immune response absence of unexpected results because Yung [sic] already discloses that Hsp70 family fusion proteins are generally useful as immunogens for stimulating CD8+ CTL and Siegel et al particularly demonstrate a portion of Hsp70, which is a homolog of SEQ ID NO: 8 is suitable for conjugating a viral antigen to produce an enhanced Th1 type immune response, including CD8+ CTL response absence of unpredicted result” (Office Action, page 6).

Claims 39-43, 54-58 and 68-86 have been canceled, and the language “a homolog thereof” has been deleted from Claims 36, 37 and 53. Neither U.S. Patent No. 6,338,952 (referred to herein as Young) nor Siegel *et al.* teaches a composition comprising a portion of a heat shock protein (hsp), wherein: the portion of the hsp is joined to a heterologous protein; the portion of the hsp is limited to SEQ ID NO:8; and the composition, when administered to an animal in a physiologically acceptable formulation, elicits a CD8<sup>+</sup> cytotoxic T lymphocyte (CTL)

response that is greater than the response elicited by administration of the heterologous protein alone.

The combined teaching of Young and Siegel *et al.* does not render obvious Applicants' claimed invention, particularly as amended.

Rejection of Claims 36-39, 43-46, 53, 54, 59-61, 68-73 and 77-80 under 35 U.S.C. §102(e)

Claims 36-39, 43-46, 53, 54, 59-61, 68-73 and 77-80 are rejected under 35 U.S.C. §102(e) "as being anticipated by Siegel et al. (US Patent No. 6,495,347B1)" (Office Action, page 7). The Examiner states that Siegel *et al.* disclose a fusion protein made from conjugated Hsp65, 40, 10, 60 and 71 with a heterologous sequence encoding a human viral antigenic polypeptide and "use a portion of M Tuberculosis Hsp of SEQ ID NO: 41 or SEQ ID NO: 45, which have more than 99% homology to the portion of M Tuberculosis Hsp" of Applicants' SEQ ID NO: 8 (Office Action, page 7).

The language "a homolog thereof", "homolog", "substitution mutant" or "fragment" of SEQ ID NO: 8 has been deleted from the claims, thereby obviating the rejection. Siegel *et al.* do not teach a composition comprising a portion of a heat shock protein (hsp), wherein: the portion of the hsp is joined to a heterologous protein; the portion of the hsp is limited to SEQ ID NO:8; and the composition, when administered to an animal in a physiologically acceptable formulation, elicits a CD8<sup>+</sup> cytotoxic T lymphocyte (CTL) response that is greater than the response elicited by administration of the heterologous protein alone.

Siegel *et al.* do not anticipate Applicants' claimed invention, particularly as amended.

Rejection of Claims 63-86 under 35 U.S.C. §103(a)

Claims 63-86 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Young (WO 98/35705A1) and Siegel et al. (US Patent No. 6,495347B1)" (Office Action, page 8). The Examiner states that it would have been obvious to one of ordinary skill in the art "to make immunogenic composition comprising Hsp70 fusion protein, such as the Hsp homologous protein of SEQ ID NO: 8 homolog that is conjugated with any viral antigen or bacterial antigen as well as biologically active moiety including toxin or glycoprotein as taught by Young and use the composition to induce an enhanced CD8+ T cell mediated CTL immune response absence of

unexpected results because Yung [sic] already discloses that Hsp70 family fusion proteins are generally useful as immunogens for stimulating CD8+ CTL and Siegel et al particularly demonstrate that Hsp that is s [sic] homolog of SEQ ID NO: 8 is suitable for conjugating a viral antigen for producing an enhanced Th1 type immune response, including CD8<sup>+</sup> CTL response" (Office Action, page 9).

The language "a homolog thereof" and "homolog" of SEQ ID NO: 8 has been deleted from the claims, thereby obviating the rejection. Neither Young nor Siegel *et al.* teaches a composition comprising a portion of a heat shock protein (hsp), wherein: the portion of the hsp is joined to a heterologous protein; the portion of the hsp is limited to SEQ ID NO:8; and the composition, when administered to an animal in a physiologically acceptable formulation, elicits a CD8<sup>+</sup> cytotoxic T lymphocyte (CTL) response that is greater than the response elicited by administration of the heterologous protein alone.

The combined teaching of Young and Siegel *et al.* does not render obvious Applicants' claimed invention, particularly as amended.

### CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Anne J. Collins  
Anne J. Collins  
Registration No. 40,564  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: March 17, 2004